

K070740

MAY - 7 2007

SPECIAL 510(k)

510(k) SUMMARY

Chad Therapeutics, Inc.

**Chad Therapeutics Bonsai Model 800
(Modified Chad Therapeutics OXYPNEUMATIC CYPRESS Model 511)**

Date Prepared: March 14, 2007

Submitter Information: Chad Therapeutics, Inc.
21622 Plummer Street
Chatsworth, CA 91311

Official Contact: Kevin McCulloh
Executive Vice President
Vice President of Engineering
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Proprietary Names: Chad Therapeutics Bonsai Model 800

Common Name: Oxygen conserver

Classification Name: Non-continuous ventilator

Classification Reference: Class II, 21 CFR 868.5905

Product Code: NFB

Predicate Device Equivalence:

Substantial equivalence is claimed to the Chad Therapeutics Unmodified OXYPNEUMATIC CYPRESS 511, cleared for commercial distribution per K020475.

Device Description:

The Chad Therapeutics Bonsai is a pneumatic-controlled device, which is a combination of a low-pressure regulator and an oxygen conserver, designed for use with ambulatory oxygen systems. It delivers boluses of oxygen that is equivalent to 1 to 7 liters per minute, depending on the flow rate setting.

Intended Use:

The Chad Therapeutics, Inc. Bonsai is intended for prescription use only to be used as part of a portable oxygen delivery system for patients that require supplemental oxygen in their home and for ambulatory use.

Comparison of Technological Characteristics:

The Chad Therapeutics Bonsai Model 800 has the same technological characteristics as the predicate devices. The hardware has been modified to reduce the size and weight of regulator portion. The hardware has been modified to include an additional flow setting and the bolus sizes have been modified to be similar to the Chad Therapeutics OXYMATIC 24 (K884562). In addition the labeling has been modified. Major portions of the patient inhalation detection sensor diaphragm and oxygen delivery portion of the device are identical to the primary predicate device.

Summary of Testing:

All risk assessment, design verification and validation activities were conducted in accordance with the device product requirements to demonstrate that the Chad Therapeutics Bonsai would perform as intended.

- ✓ The regulator in the device passed the ASTM G 175-03 Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications safety test.
- ✓ The Bonsai passed all of the test criteria established in the Bonsai design verification and validation tests.

Substantial Equivalence:

Based on the above, we concluded that the Chad Therapeutics modified OXYPNEUMATIC CYPRESS Model 511 (i.e., the Bonsai Model 800) are substantially equivalent to unmodified OXYPNEUMATIC CYPRESS 511 devices and are safe and effective for their intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Kevin McCulloh
Vice President of Engineering
Chad Therapeutics, Incorporated
21622 Plummer Street
Chatsworth, California 91311

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Re: K070740

Trade/Device Name: Chad Therapeutics Bonsai Model 800 (Modified Chad
Therapeutics OXYPNEUMATIC CYPRESS Model 511)

Regulation Number: 868.5905

Regulation Name: Noncontinuous Ventilator (IPPB)

Regulatory Class: II

Product Code: NFB

Dated: April 21, 2007

Received: April 24, 2007

Dear Mr. McCulloh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

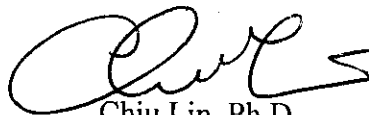
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Chad Therapeutics Bonsai Model 800 (modified Chad Therapeutics OXYPNEUMATIC CYPRESS Model 511).

Indications For Use:

The Chad Therapeutics Bonsai (modified Chad Therapeutics OXYPNEUMATIC CYPRESS Model 511) is intended for use in the same manner as the unmodified device, i.e., for prescription use only, to be used as part of a portable oxygen delivery system for patients that require supplemental oxygen in their home and for ambulatory use.

Prescription Use ☒
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
 (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Charlotte

(in Sign-Off)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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